

PATENT/Docket No. 01559.US1

Serial No. 10/803,146

Amendment dated 8/19/2004

Second Preliminary Amendment

**AMENDMENTS TO THE CLAIMS**

This listing of claims replaces all prior versions and listings of claims in the application.

**Listing of Claims**

Claims 1-15 (canceled)

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16. (Previously presented) A method of treatment and/or prevention of an inflammatory condition in a fluid-containing organ having a natural exterior orifice, the method comprising administering a pharmaceutical composition comprising an anti-inflammatory agent to the organ via the exterior orifice, said composition further comprising a vehicle that comprises (a) an amphipathic oil that is water dispersible and ethanol insoluble, (b) microcrystalline wax and (c) a pharmaceutically acceptable non-aqueous carrier.
17. (Previously presented) The method of Claim 16 wherein the fluid-containing organ is an udder of a milk producing animal, and wherein the composition is administered by intramammary infusion.
18. (Previously presented) The method of Claim 17 wherein the inflammatory condition is associated with mastitis.
19. (Previously presented) The method of Claim 16 wherein the fluid-containing organ is an ear of a subject, and wherein the composition is administered by otic infusion.
20. (Previously presented) The method of Claim 19 wherein the inflammatory condition is associated with an otic disorder selected from the group consisting of otitis externa, otitis media, otorrhea, acute mastoiditis, infections related to otic surgical procedures, otosclerosis, otalgia, otic pain, otic inflammation, otic bleeding, Lermoyez's syndrome, Meniere's disease, vestibular neuronitis, benign paroxysmal positional vertigo, herpes zoster oticus, Ramsay Hunt's syndrome, viral neuronitis, ganglionitis, geniculate herpes, labyrinthitis, including purulent labyrinthitis and viral endolymphatic labyrinthitis, perilymph fistulas, presbycusis, drug-induced ototoxicity, acoustic neuromas, aerotitis media, infectious myringitis, bullous myringitis, otic neoplasm, squamous cell carcinoma, basal cell carcinoma, other otic

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cancers, pre-cancerous otic conditions, nonchromaffin paragangliomas, chemodectomas, glomus jugulare tumors, glomus tympanicum tumors, perichondritis, aural eczematoid dermatitis, malignant external otitis, subperichondrial hematoma, ceruminomas, impacted cerumen, sebaceous cysts, osteomas, keloids, tinnitus, vertigo, tympanic membrane infection, tympanitis, otic furuncles, petrositis, conductive and sensorineural hearing loss, epidural abscess, lateral sinus thrombosis, subdural empyema, otitic hydrocephalus, Dandy's syndrome, bullous myringitis, diffuse external otitis, foreign bodies, keratosis obturans, otomycosis, trauma, acute barotitis media, acute eustachian tube obstruction, postsurgical otalgia, and complications associated therewith.

21. (Previously presented) The method of Claim 19 wherein the inflammatory condition is associated with an otic disorder selected from the group consisting of otitis externa, otitis media, otorrhea, and infections having an inflammatory component that are related to an otic surgical procedure.
22. (Previously presented) The method of Claim 16 wherein the anti-inflammatory agent is selected from the group consisting of aceclofenac, acemetacin, *e*-acetamidocaproic acid, acetaminophen, acetaminosalol, acetanilide, acetylsalicylic acid, *S*-adenosylmethionine, alclofenac, alclometasone, alfentanil, algestone, allylprodine, alminoprofen, aloxiprin, alphaprodine, aluminum bis(acetylsalicylate), amcinonide, amfenac, aminochlorphenoxazin, 3-amino-4-hydroxybutyric acid, 2-amino-4-picoline, aminopropylon, aminopyrine, amixetrine, ammonium salicylate, ampiroxicam, amtolmetin guacil, anileridine, antipyrine, antrafenine, apazone, beclomethasone, bendazac, benorylate, benoxaprofen, benzpiperylon, benzydamine, benzylmorphine, bermoprofen, betamethasone, betamethasone-17-valerate, bezitramide,  $\alpha$ -bisabolol, bromfenac, *p*-bromoacetanilide, 5-bromosalicylic acid acetate, bromosaligenin, bucetin, buclocic acid, bucolome, budesonide, bufexamac, bumadizon, buprenorphine, butacetin, butibufen, butorphanol, carbamazepine, carbiphene, carprofen, carsalam, chlorobutanol, chloroprednisone, chlorthenoxazin, choline salicylate, cinchophen, cinmetacin, ciramadol, clidanac, clobetasol, clocortolone,

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clometacin, clonitazene, clonixin, clopirac, cloprednol, clove, codeine, codeine methyl bromide, codeine phosphate, codeine sulfate, cortisone, cortivazol, cropropamide, crotethamide, cyclazocine, deflazacort, dehydrotestosterone, desomorphine, desonide, desoximetasone, dexamethasone, dexamethasone-21-isonicotinate, dexoxadrol, dextromoramide, dextropropoxyphene, deoxycorticosterone, dezocine, diampromide, diamorphone, diclofenac, difenamizole, difenpiramide, diflorasone, diflucortolone, diflunisal, difluprednate, dihydrocodeine, dihydrocodeinone enol acetate, dihydromorphine, dihydroxyaluminum acetylsalicylate, dimenoxadol, dimepheptanol, dimethylthiambutene, dioxaphetyl butyrate, dipipanone, diprocetyl, dipyrone, ditazol, droxicam, emorfazone, enfenamic acid, enoxolone, epirizole, epitazocine, etersalate, ethenzamide, ethoheptazine, ethoxazene, ethylmethylthiambutene, ethylmorphine, etodolac, etofenamate, etonitazene, eugenol, felbinac, fenbufen, fenclozic acid, fendosal, fenoprofen, fentanyl, fentiazac, fepradinol, feprazone, floctafenine, fluazacort, flucloronide, flufenamic acid, flumethasone, flunisolide, flunixin, flunoxaprofen, fluocinolone acetonide, fluocinonide, fluocinolone acetonide, fluocortin butyl, fluocortolone, fluoresone, fluorometholone, fluperolone, flupirtine, fluprednidene, fluprednisolone, fluproquazone, flurandrenolide, flurbiprofen, fluticasone, formocortal, fosfosal, gentisic acid, glafenine, glucametacin, glycol salicylate, guaiazulene, halcinonide, halobetasol, halometasone, haloprednone, heroin, hydrocodone, hydrocortamate, hydrocortisone, hydrocortisone acetate, hydrocortisone succinate, hydrocortisone hemisuccinate, hydrocortisone 21-lysinate, hydrocortisone cypionate, hydromorphone, hydroxypethidine, ibufenac, ibuprofen, ibuproxam, imidazole salicylate, indomethacin, indoprofen, isofezolac, isoflupredone, isoflupredone acetate, isoladol, isomethadone, isonixin, isoxepac, isoxicam, ketobemidone, ketoprofen, ketorolac, *p*-lactophenetide, lefetamine, levallorphan, levorphanol, levophenacyl-morphan, lofentaniol, lonazolac, lornoxicam, loxoprofen, lysine acetylsalicylate, mazipredone, meclofenamic acid, medrysone, mefenamic acid, meloxicam, meperidine, meprednisone, meptazinol, mesalamine,

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metazocine, methadone, methotrimeprazine, methylprednisolone, methylprednisolone acetate, methylprednisolone sodium succinate, methylprednisolone suleptnate, metiazinic acid, metofoline, metopon, mofebutazone, mofezolac, mometasone, morazone, morphine, morphine hydrochloride, morphine sulfate, morpholine salicylate, myrophine, nabumetone, nalbuphine, nalorphine, 1-naphthyl salicylate, naproxen, narceine, nefopam, nicomorphine, nifenazone, niflumic acid, nimesulide, 5'-nitro-2'-propoxyacetanilide, norlevorphanol, normethadone, normorphine, norpipanone, olsalazine, opium, oxaceprol, oxametacine, oxaprozin, oxycodone, oxymorphone, oxyphenbutazone, papaveretum, paramethasone, paranyline, parsalimide, pentazocine, perisoxal, phenacetin, phenadoxone, phenazocine, phenazopyridine hydrochloride, phenacetol, phenoperidine, phenopyrazone, phenomorphan, phenyl acetylsalicylate, phenylbutazone, phenyl salicylate, phenylramidol, piketoprofen, piminodine, pipebuzone, piperylone, pirofen, pirazolac, piritramide, piroxicam, pranoprofen, prednicarbate, prednisolone, prednisone, prednival, prednylidene, proglumetacin, proheptazine, promedol, propacetamol, properidine, propiram, propoxyphene, propyphenazone, proquazone, protizinic acid, proxazole, ramifenazone, remifentanil, rimazolium metilsulfate, salacetamide, salicin, salicylamide, salicylamide o-acetic acid, salicylic acid, salicylsulfuric acid, salsalate, salverine, simetride, sufentanil, sulfasalazine, sulindac, superoxide dismutase, suprofen, suxibuzone, talniflumate, tenidap, tenoxicam, terofenamate, tetrandrine, thiazolinobutazone, tiaprofenic acid, tiaramide, tilidine, tinoridine, tixocortol, tolfenamic acid, tolmetin, tramadol, triamcinolone, triamcinolone acetonide, tropesin, viminol, xenbucin, ximoprofen, zaltoprofen and zomepirac.

23. (Previously presented) The method of Claim 16 wherein the anti-inflammatory agent comprises a selective COX-2 inhibitor.
24. (Previously presented) The method of Claim 23 wherein the selective COX-2 inhibitor is selected from the group consisting of deracoxib, parecoxib, celecoxib, valdecoxib, rofecoxib, etoricoxib, lumiracoxib, 2-(3,5-difluorophenyl)-3-[4-

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(methylsulfonyl)phenyl]-2-cyclopenten-1-one, (S)-6,8-dichloro-2-(trifluoromethyl)-2H-1-benzopyran-3-carboxylic acid, 2-(3,4-difluorophenyl)-4-(3-hydroxy-3-methyl-1-butoxy)-5-[4-(methylsulfonyl)phenyl]-3-(2H)-pyridazinone, 4-[5-(4-fluorophenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]benzenesulfonamide, 4-[5-(phenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]benzenesulfonamide, salts and prodrugs thereof.

25. (Previously presented) A pharmaceutical composition comprising a vehicle that comprises (a) an amphipathic oil that is water dispersible and ethanol insoluble, (b) microcrystalline wax and (c) a pharmaceutically acceptable non-aqueous carrier, said vehicle having stably dispersed therein an anti-inflammatory agent in an anti-inflammatorily effective amount.
26. (Previously presented) The composition of Claim 25 that is suitable for intramammary infusion to an udder of a milk producing animal for treatment and/or prevention of an inflammatory condition of the udder.
27. (Previously presented) The composition of Claim 26 wherein the inflammatory condition is associated with mastitis.
28. (Previously presented) The composition of Claim 25 that is suitable for otic infusion into an ear of a subject for treatment and/or prevention of an inflammatory condition of the ear.
29. (Previously presented) The composition of Claim 28 wherein the inflammatory condition is associated with an otic disorder selected from the group consisting of otitis externa, otitis media, otorrhea, acute mastoiditis, infections related to otic surgical procedures, otosclerosis, otalgia, otic pain, otic inflammation, otic bleeding, Lermoyez's syndrome, Meniere's disease, vestibular neuronitis, benign paroxysmal positional vertigo, herpes zoster oticus, Ramsay Hunt's syndrome, viral neuronitis, ganglionitis, geniculate herpes, labyrinthitis, including purulent labyrinthitis and viral endolymphatic labyrinthitis, perilymph fistulas, presbycusis, drug-induced ototoxicity, acoustic neuromas, aerotitis media, infectious myringitis, bullous myringitis, otic neoplasm, squamous cell carcinoma, basal cell carcinoma, other otic

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30. (Previously presented) The composition of Claim 28 wherein the inflammatory condition is associated with an otic disorder selected from the group consisting of otitis externa, otitis media, otorrhea, and infections having an inflammatory component that are related to an otic surgical procedure.
31. (Previously presented) The composition of Claim 25 wherein the anti-inflammatory agent is selected from the group consisting of aceclofenac, acemetacin, *e*-acetamidocaproic acid, acetaminophen, acetaminosalol, acetanilide, acetylsalicylic acid, *S*-adenosylmethionine, alclofenac, alclometasone, alfentanil, algestone, allylprodine, alminoprofen, aloxiprin, alphaprodine, aluminum bis(acetylsalicylate), amcinonide, amfenac, aminochlorthenoxazin, 3-amino-4-hydroxybutyric acid, 2-amino-4-picoline, aminopropylon, aminopyrine, amixetrine, ammonium salicylate, ampiroxicam, amtolmetin guacil, anileridine, antipyrine, antrafenine, apazone, beclomethasone, bendazac, benorylate, benoxaprofen, benzpiperylon, benzydamine, benzylmorphine, bermoprofen, betamethasone, betamethasone-17-valerate, bezitramide,  $\alpha$ -bisabolol, bromfenac, *p*-bromoacetanilide, 5-bromosalicylic acid acetate, bromosaligenin, buccetin, buclocic acid, bucolome, budesonide, bufexamac, bumadizon, buprenorphine, butacetin, butibufen, butorphanol, carbamazepine, carbiphene, carprofen, carsalam, chlorobutanol, chloroprednisone, chlorthenoxazin, choline salicylate, cinchophen, cimmetacin, ciramadol, clidanac, clobetasol,

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32. (Previously presented) The composition of Claim 25 wherein the anti-inflammatory agent comprises a steroid.
33. (Previously presented) The composition of Claim 25 wherein the anti-inflammatory agent comprises a non-steroidal anti-inflammatory drug.

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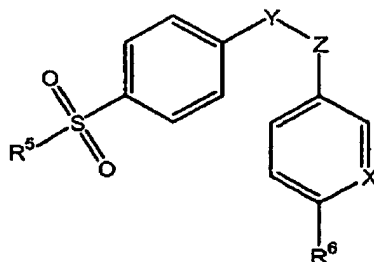
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34. (Previously presented) The composition of Claim 25 wherein the anti-inflammatory agent comprises a selective COX-2 inhibitor.
35. (Previously presented) The composition of Claim 34 wherein the selective COX-2 inhibitor is a compound having the formula



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where  $R^5$  is a methyl or amino group,  $R^6$  is hydrogen or a  $C_{1-4}$  alkyl or alkoxy group,  $X'$  is N or  $CR^7$  where  $R^7$  is hydrogen or halogen, and Y and Z are independently carbon or nitrogen atoms defining adjacent atoms of a five- to six-membered ring that is optionally substituted at one or more positions with oxo, halo, methyl or halomethyl groups.

36. (Previously presented) The composition of Claim 34 wherein the selective COX-2 inhibitor is selected from the group consisting of deracoxib, parecoxib, celecoxib, valdecoxib, rofecoxib, etoricoxib, lumiracoxib, 2-(3,5-difluorophenyl)-3-[4-(methylsulfonyl)phenyl]-2-cyclopenten-1-one, (S)-6,8-dichloro-2-(trifluoromethyl)-2H-1-benzopyran-3-carboxylic acid, 2-(3,4-difluorophenyl)-4-(3-hydroxy-3-methyl-1-butoxy)-5-[4-(methylsulfonyl)phenyl]-3-(2H)-pyridazinone, 4-[5-(4-fluorophenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]benzenesulfonamide, 4-[5-(phenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]benzenesulfonamide, salts and prodrugs thereof.
37. (Previously presented) The composition of Claim 34 wherein said selective COX-2 inhibitor is present at a concentration of 0.01 to 1000 mg/ml.
38. (Previously presented) The composition of Claim 34 wherein said selective COX-2 inhibitor is present at a concentration of 0.1 to 750 mg/ml.
39. (Previously presented) The composition of Claim 34 wherein said selective COX-2

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inhibitor is present at a concentration of 5 to 250 mg/ml.

40. (Currently amended) The composition of ~~any of Claims 25-39~~ Claim 25 wherein the amphipathic oil is a polyglycolized glyceride prepared by an alcoholysis reaction of natural triglycerides with polyethylene glycols.
41. (Previously presented) The composition of Claim 40 wherein the polyglycolized glyceride comprises a main fatty acid component of oleic acid or linoleic acid.
42. (Previously presented) The composition of Claim 40 wherein the polyglycolized glyceride comprises a main fatty acid component of oleic acid.
43. (Previously presented) The composition of Claim 40 wherein the polyglycolized glyceride is pegicol 5-oleate.
44. (Currently amended) The composition of Claim ~~[[40]]~~ 25 wherein the amphipathic oil constitutes 0.01% to 99% weight/volume of the composition.
45. (Currently amended) The composition of Claim ~~[[40]]~~ 25 wherein the amphipathic oil constitutes 1% to 80% weight/volume of the composition.
46. (Previously presented) The composition of Claim 25 wherein the amphipathic oil constitutes 3% to 25% weight/volume of the composition.
47. (Previously presented) The composition of Claim 25 wherein the microcrystalline wax constitutes 0.001% to 50% weight/volume of the composition.
48. (Previously presented) The composition of Claim 25 wherein the microcrystalline wax constitutes 0.1% to 40% weight/volume of the composition.
49. (Previously presented) The composition of Claim 25 wherein the microcrystalline wax constitutes 1% to 15% weight/volume of the composition.
50. (Currently amended) The composition of ~~any of Claims 25-39~~ Claim 25 wherein the non-aqueous carrier is selected from the group consisting of vegetable oils, mineral oils, medium to long chain fatty acids and alkyl esters thereof, propylene glycol diesters of medium to long chain fatty acids, mono-, di-, and triglyceryl esters of fatty

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acids, polyethylene glycols, and combinations thereof.

51. (Previously presented) The composition of Claim 50 wherein the non-aqueous carrier is a vegetable oil selected from the group consisting of cottonseed oil, corn oil, sesame oil, soybean oil, olive oil, coconut oil, fractionated coconut oils, peanut oil, sunflower oil, safflower oil, almond oil, avocado oil, palm oil, palm kernel oil, babassu oil, beechnut oil, linseed oil, rape oil and combinations thereof.
52. (Previously presented) The composition of Claim 50 wherein the non-aqueous carrier is cottonseed oil.
53. (Previously presented) The composition of Claim 50 wherein the non-aqueous carrier comprises capric acid in an amount of 20% to 45% and caprylic acid in an amount of 45% to 80% by weight of the non-aqueous carrier.
54. (Currently amended) The composition of Claim ~~[[50]]25~~ wherein the non-aqueous carrier constitutes 0.5% to 99% weight/volume of the composition.
55. (Currently amended) The composition of Claim ~~[[50]]25~~ wherein the non-aqueous carrier constitutes 10% to 95% weight/volume of the composition.
56. (Currently amended) The composition of Claim ~~[[50]]25~~ wherein the non-aqueous carrier constitutes 40% to 90% weight/volume of the composition.
57. (Currently amended) The composition of ~~any of Claims 25-39~~ Claim 25 that further comprises at least one excipient selected from the group consisting of antioxidants, preservatives, stabilizers, wetting agents, lubricants, emulsifiers, salts for influencing osmotic pressure, coloring agents, alcohols and buffering agents.
58. (Previously presented) The composition of Claim 25 wherein the polyglycolized glyceride is pegicol 5-oleate; the non-aqueous carrier is cottonseed oil; and the anti-inflammatory agent comprises a selective COX-2 inhibitor.
59. (Previously presented) An article of manufacture comprising a container or delivery device having an oxygen permeable wall, and having contained therein the composition of Claim 25.

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60. (Previously presented) The article of Claim 59 wherein said wall is constructed of an oxygen permeable material comprising polyethylene.
61. (Previously presented) The article of Claim 59 wherein the composition exhibits extended chemical and/or physical stability.

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